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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,462	02/05/2007	Ryuji Ueno	Q76937	1105

23373 7590 09/29/2011

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EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1627	

NOTIFICATION DATE	DELIVERY MODE
09/29/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/567,462	UENO ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *14-16 and 18-28* is/are pending in the application.

5a) Of the above claim(s) *18-20* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *14-16 and 21-28* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of July 21, 2011 made to the office action filed April 21, 2011. Claims 14-16 and 18-28 are pending. Claims 18-20 are withdrawn. Claims 25-28 are new. Claim 14-16 and 18-24 are amended. Claims 14-60 and 21-28 are examined on the merits in light of the Applicant's species election of 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF2α isopropyl ester in the reply filed on September 17, 2009.

The Declaration was fully considered but was not found persuasive to overcome the rejections.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 U.S.C. 103(a) rejection over Johnstone and Skuballa et al. were found not persuasive, thus the rejection is upheld.

Due to the new amendments to the claims the new and modified 35 U.S.C. 103(a) rejection are below. The Examiner has addressed the Applicant's arguments and Declaration below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 14-16 and 21-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnstone (US 6,262,105 B1) in view of Skuballa et al. (US 4,088,775).

Johnstone teach that prostaglandin PGFα2 compounds stimulate hair growth (see abstract, column 9, lines 1-55 and claim 9; addresses claim 9). Particularly, PGFα analogues stimulate cell surface receptors, which activate a family of protein kinases that are fundamental in cell growth (see column 8, lines 19-27). PGFα analogues also alter tensegrity that can direct induction of DNA replication and stimulate cell division, prevention of apoptosis and prolong the hair cycle. By increasing the duration of the cell cycle, the interval in the anagen phase may be increased permitting hypertrophy of the follicles with longer and thicker hairs (see column 8, lines 29-33 and 50-59). The stimulation of hair growth is provided for the hair of the scalp, eyebrows, beard and other areas that contain hair that results in increased hair growth in the corresponding areas (see column 7, lines 60-65; addresses claims 21-24). The compounds are applied from about 0.0000001% to about 50% (see claims 2 and 6; addresses claims 25, 26 and 28).

Johnstone does not teach the specific elected compound 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF2α isopropyl ester, or the specific range of 0.001-0.1% of the compound.

Skuballa et al. teach that compounds like 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF2α isopropyl ester (see column 3, lines 1-48) have an activity spectrum similar to but stronger and longer lasting activity than the corresponding natural prostaglandins (see abstract). Particularly, it is generally known that the physiological effects of the

prostaglandins are only of short duration in the mammalian organism as well as in vitro, since they are rapidly converted into pharmacologically inactive metabolic products. Thus, a physiologically inactive metabolite is formed by oxidation of the allylic hydroxy function on the C-15 atom (see column 2, lines 21-34). The novel ketals surpass in their activity the natural prostaglandins. Furthermore, the effectiveness lasts over a longer period of time. The 15-ketoprostaglandins corresponding to these ketals show the physiological effects typical for prostaglandins only in greatly weakened form. Therefore, the advantageous properties of the novel compounds could not be expected (see column 2, last paragraph).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the teaching of Johnstone and 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF2α isopropyl ester because Skuballa et al. teach that compounds such as the elected compound have an activity spectrum similar to but stronger and longer lasting activity than the corresponding natural prostaglandins (see abstract) because they are not easily metabolized (see column 2, lines 21-34) to the inactive prostaglandin. The 15-ketoprostaglandins corresponding to these ketals show the physiological effects typical for prostaglandins only in greatly weakened form. Therefore, the advantageous properties of the ketals could not be expected (see column 2, last paragraph). Thus, one skilled in the art would expect 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF2α isopropyl ester to have similar activities as taught

in Johnstone because it is a PGF2α derivative, in which should have better activity as then other PGF2α derivatives because of the teachings of Skuballa et al.

In regards to the amounts of the compound, Johnstone teaches that the compounds are active to stimulate hair growth from about 0.0000001% to about 50% (see claims 2 and 6). Thus, Johnstone teaches a range that overlaps the Applicant's range. It is considered within the skill of the art to optimize the amount of the active compound through routine experimentation. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) It is the normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. See In re Boesch, 617 F.2d 272, 276, 205 USPQ 215, 219 (CCPA 1980) ("[D]iscovery of an optimum value of the result effective variable in a known process is ordinarily within the skill of the art." See, e.g., In re Baird, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994); In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). *In re Paterson* Appeal No. 02-1189 (Fed. Cir. January 8, 2003).

Response to Arguments

Declaration

> Mr. Tabuchi demonstrates that the Johnstone compound Latonoprost (having a 15-hydroxyl) at 0.005% has a better effect to growing hair than the 15-ketal of latanoprost at 0.01%. One would not have been motivated to modify Johnstone to arrive at the present invention. Further the 15-keto of latanoprost is not effective, so this is another reason why one would not have been motivated to substitute 15-ketal, which is not even disclosed in Johnstone.

The Examiner has fully considered the declaration but does not find the results persuasive to overcome the rejections. First, when comparing Latanoprost at 0.005% after 28 days the mice had +++, ++ or + hair growth (more +'s indicate more hair growth), whereas as at 28 days with 0.01% of the ketal (compound B) the mice had ++, +++ or ++. Thus, showing that the ketal is superior. The same trend is found at 30 days of treatment. If one compares equal concentrations of the ketal and Latanoprost (15-hydroxyl) the ketal is also superior to the 15-hydroxyl. Particularly, at 0.01% of Latanoprost after 30 days the mice had ++, ++ or + of hair growth, whereas after 30 days at 0.01% of the ketal the mice had +++, +++, or ++ hair growth. The 15-keto compound of Latanoprost having no hair growth activity is not surprising as well. The above results are not considered unexpected because of the Skuballa et al. teachings. Particularly, Skuballa et al. teaches that the ketal is superior to the hydroxyl or the carbonyl at the 15-position. The 15-hydroxyl prostaglandins are oxidized in the body to the 15-keto which show much less effectiveness than the ketal form. Thus, one would be motivated to protect the 15-hydroxyl compound of Johnstone from oxidation to the ketone by converting it to the ketal as taught by Skuballa et al. (see column 2, lines 21-30 and 58-63).

Rejection

> The Applicant argues points discussed in the declaration above. Further, there is no suggestion in Johnstone to choose a PG derivative having no ring moiety on the omega chain for promoting hair growth. Additionally, the Applicants have submitted unexpected superiority for all ranges. Additionally, the Applicants have provided further unexpected results of increased hair growth without the side effect of decreasing the IOP, thus making it superior to Johnstone's invention. It is better to avoid side effect while providing treatment especially in patients that do not have glaucoma. Lastly, the claims have been amended to include only eyelash growth which would affect non-glaucoma patients.

The Examiner disagrees for the same reason as given for the arguments toward the presently filed Declaration. One skilled in the art would be motivated to use the Applicant's elected compound over the compounds of Johnstone because Skuballa et al. teach that compounds, such as the elected compound, have an activity spectrum similar to but stronger and longer lasting activity than the corresponding natural prostaglandins (see abstract). Particularly, the compounds like the Applicant's elected compound are not easily metabolized (see column 2, lines 21-34) to the inactive prostaglandin. Skuballa et al. provides clear motivation to make the ketal analogue because it is superior to the hydroxyl or the carbonyl at the 15-position. Thus, one skilled in the art would expect 13,14-dihydro-15,15-ethylenedioxy-20-ethyl PGF2α isopropyl ester to have similar activities as taught in Johnstone because it is a PGF2α derivative, in which should have better activity as then other PGF2α derivatives taught in claim 9 of Johnstone because of the teachings of Skuballa et al. The teachings of Johnstone are not limited to the examples. The claims of Johnstone clearly cover the applicant's compound wherein the alkyl group is not substituted with a phenyl group

because R2 can be H in each of Johnstone's claims 1, 5 and 9. Skuballa et al. provides the motivation to make the elected ketal. Regarding the IOP effect, this effect may not deter one skilled in the art to use the compounds since Johnstone apparently teaches that these compounds are effective in growing hair even with this effect. Sometimes side effects are tolerated because of the usefulness of the treatment. It is important to note that the Applicant's comparison was made between the 15-keto and the 15-ketal, whereas Johnstone teaches the 15-hydroxyl. Therefore, it is not clear that the compounds of Johnstone effect the IOP. Nevertheless, the Examiner has still provided reason for why one would still use the compounds as taught by Johnstone in view of Skuballa et al. Particularly, reduced IOP is useful in the population of patients that have glaucoma (see Johnstone, column 3, lines 50-56). Further, the present invention and Johnstone is not limited to the growth of eyelashes. The composition of Johnstone can be used as creams and applied to the scalp and other areas that hair grows. Likewise, the Applicant's invention is not limited to eyelash growth in the independent claim. Thus, the compounds of Johnstone in view of Skuballa et al. are still useful for hair growth for eyelashes in glaucoma patients and for the growth of hair on the scalp in patients in general. In regards to the effective amount of the Applicant's compounds, the Examiner agrees that the specification demonstrates effectiveness of hair growth at concentrations of 0.01 and 0.1% (see pages 31-34).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kendra D Carter
Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627